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In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-605

UNITED STATES OF AMERICA, ET AL.,
Petitioners,

VERSUS

GLEN L. RUTHERFORD, ET AL.,
Respondents.

On Writ of Certiorari to the United States
Court of Appeals for the Tenth Circuit

BRIEF OF RESPONDENTS

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RESPONDENTS' BRIEF

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-7a) is reported at 582 F.2d 1234. The opinion of the district court (Pet. App. 11a-44a) is reported at 438 F.Supp. 1287. The decision of the Commissioner of Food and Drugs (Pet. App. 45a-274a) is reported at 42 Fed. Reg. 39768.

JURISDICTION

The judgment of the court of appeals (Pet. App. 8a-9a) was entered on July 10, 1978. On August 4, 1978, the court of appeals denied a Motion for Clarification or in the alternative Petition for Re-Hearing filed by respondents (Pet. App. 10a). The Petition for a Writ of Certiorari was filed on October 10, 1978, and granted on January 22, 1979. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the safety and effectiveness requirements of the Federal Food, Drug, and Cosmetic Act apply to terminally ill cancer patients desirous of taking Laetrile.
2. Whether Laetrile is exempt from the pre-market clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the transitional provisions of the 1962 amendments to the Act (generally referred to as the 1962 grandfather clause).
3. Whether the Food and Drug Administration prohibition of the use of Laetrile by a class of terminally ill cancer patients violates those patients' Constitutionally guaranteed right of privacy.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Amendment I to the United States Constitution.
2. Amendment IV to the United States Constitution.
3. Amendment V to the United States Constitution.
4. Amendment IX to the United States Constitution.
5. Amendment XIV to the United States Constitution.
6. 21 U.S.C.A. Section 321(g)(1):

"The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or preven-

tion of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

7. 21 U.S.C.A., Section 321(p), provides in pertinent part:

"The term 'new drug' means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof,"

8. Section 107(c)(4) of the Drug Amendments of 1962, Pub. L. No. 87-781 (76 Stat. 789) (1962 grandfather clause) provides:

"In the case of any drug which, on the day immediately preceding the enactment date [October 10, 1962] (A) was commercially used or sold in the United States, (B) was not a new drug as defined by Section 201(p) of the basic Act as then in force [21 U.S.C.A. 321(p)] and (C) was not covered by an effective [new drug] application under Section 505 of that [Act 21 U.S.C. 355], the amendments to Section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

9. 5 U.S.C.A., Section 706, Scope of review:

"To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - (B) contrary to constitutional right, power, privilege, or immunity;
 - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
 - (D) without observance of procedure required by law;
 - (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
 - (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."

STATEMENT

This action was instituted by cancer patients on March 12, 1975, seeking to enjoin the Government from interfering with the sale and distribution of Laetrile for the personal use of individual cancer patients. In August, 1975, the district court issued a preliminary injunction enjoining the Government from preventing the purchase and interstate transportation of a limited quantity of Laetrile for the personal use of Glen L. Rutherford.

The decision granting this preliminary injunction was appealed by the Government to the Tenth Circuit Court of Appeals, which upheld the injunction but reached the conclusion that the Federal Food and Drug Administration most probably had not developed a sufficient administrative record on the subject of Laetrile to properly formulate its opinion that Laetrile was a "new drug." Therefore, the court of appeals ordered the district court to remand the case to the Food and Drug Administration for proper proceedings if a determination was made that the Food and Drug Administration had not developed a proper administrative record.

At a hearing held on December 30, 1976, the district court determined that a competent administrative record did not exist and then in response to the court's request that the FDA make available the written basis of the agency's determination with regard to Laetrile, no matter how casual or unstructured its form or content might be, the court was advised that no such rationale existed in any form. Based upon the lack of an administrative record the district court remanded the action to the Food and Drug Administration for proper administrative proceedings.

On remand to the Food and Drug Administration, an administrative proceeding of sorts was conducted with the Commissioner finally concluding as follows:

- (a) That Laetrile is a "drug."
- (b) That Laetrile is a "new drug."
- (c) That Laetrile does not satisfy the pre-marketing approval requirements for new drugs.
- (d) That there is an absence of scientifically sound data upon which experts could base an opinion that Laetrile is safe for use in man.
- (e) That Laetrile did not meet the statutory criteria of either the 1938 or 1962 grandfather exemptions.
- (f) That Laetrile is not safe and effective.

Respondents sought judicial review of the Commissioner's decision before the Honorable Judge Luther Bohanon. Judge Bohanon vacated and set aside the agency decision and issued an injunctive order exempting Laetrile from the new drug requirements.

The district court sustained the portions of the Commissioner's conclusion that Laetrile is not generally recognized as safe and effective but determined that Laetrile would be exempt from the Act's pre-market approval requirements by virtue of an exclusion under the 1962 grandfather clause. The court further concluded that to deny respondents' use of a non-toxic substance in connection with their own personal health care offended the constitu-

tional right of privacy and, therefore, ruled that it would be unconstitutional to deny the use of Laetrile to a "terminal" cancer patient.

The Government appealed this decision to the Tenth Circuit Court of Appeals which declined to rule on either the 1962 "grandfather clause" exemption or the constitutional right to privacy relied upon by the lower court. Instead, the Tenth Circuit ruled that the "safety" and "effectiveness" requirements of the statute have no application to terminally ill cancer patients who desire to take Laetrile intravenously.

The Tenth Circuit Court of Appeals entered its order holding that the lower court's permanent injunction should be continued but limited to procurement of intravenous injections administered by a licensed medical practitioner to persons certified to be terminally ill of cancer in some form. The court then remanded the case to the lower court for further proceedings consistent with its findings. The court noted that it was "confident that the FDA with all care and due dispatch will promulgate regulations within the above limitations and as if the drug was found by the Commission to be 'safe' and 'effective' " for the limited group considered.

The decision of the Tenth Circuit Court of Appeals was appealed to the United States Supreme Court. Certiorari was granted on January 22, 1979.

SUMMARY OF ARGUMENT

Initially, it is of great import to define clearly the parameters of the lower courts' opinions.

Neither the opinion of the district court nor the Tenth Circuit Court of Appeals purports to overrule or even challenge the Federal Food, Drug, and Cosmetic Act. Rather, both opinions apply solely to the ruling of the Commissioner relative to Laetrile.

At this point in the litigation the lower courts' exclusion of Laetrile from the Federal Food, Drug, and Cosmetic Act is inherently restricted by the following requirements:

- (1) The rulings apply only to Laetrile.
- (2) The rulings apply only to usage of the liquid form of Laetrile.
- (3) The rulings apply only to terminal patients.
- (4) The rulings apply only to cancer patients.
- (5) The rulings apply only to Laetrile as it is administered by a qualified practitioner."

(1) The Commissioner has taken the unchanging and dogmatic opinion that no exemption for "terminally ill cancer patients" is found within the Federal Food, Drug, and Cosmetic Act and, therefore, no matter what the evidence is, such exception will not be found. The Federal Food, Drug, and Cosmetic Act as well as being subject to enforcement by the Food and Drug Administration is also subject to judicial interpretation. *Weinberger v. Hynscn, Westcott & Dunning*, 412 U.S. 609 (1973).

Notwithstanding the Government's argument that the term "terminal" is difficult of definition, it is a term which is used by medical practitioners on a daily basis and which has a well defined meaning within the medical profession. The only variation implicit in the term is the time frame within which the terminal illness will eventually result in death. As to "terminal cancer patients" an application of the Act's requirements of "efficacy" would lead to an absurd result and, therefore, the Act should be held inapplicable to such patients. *Trans Alaska Pipeline Rate Case*, 436 U.S. 631, 643 (1978).

The term "terminal" connotes a state of being for an individual which is inconsistent with "effective" remedies. The word "terminal" by its very definition precludes the existence of approved effective drugs else the patient would not be so classified.

The term "safe" although having some meaning to the plaintiff class of terminally ill cancer patients could only be construed to have a meaning very much removed from the meaning sought to be applied by the Food and Drug Administration.¹

¹ In this regard it should be observed that the FDA recognizes and approves the use of cancer drugs which admittedly have a potential for great harm to the cancer patient and which in some instances admittedly cause cancer as a side effect. The Physician's Desk Reference, 33rd Ed., 1979, which is a compilation of FDA approved labeling, contains the following listed drugs and the expected side effects.

CYTOXAN (Mead Johnson & Co.) — A dangerous drug which can cause death. This FDA-approved "anticancer" drug actually can also cause cancer, namely secondary malignancies. According to the FDA-approved "safety" data: "the possibility of secondary malignancy, based on available data, should be considered in any benefit-to-risk assessment for the use of the drug." In addition to causing cancer

Not even the Food and Drug Administration asserts that a drug to be "safe" cannot have certain side effects (Brief on the Merits for the United States, p. 17):

"A drug is 'unsafe' for such patients as for anyone else, if it poses risks of shortening life expectancy or aggravating symptoms that are not outweighed by potential benefits of prolonging life, improving health, or ameliorating pain."

With the above definitional limitations in mind the ruling by the District Court for the Western District of Oklahoma which was affirmed with modification by the Tenth Circuit Court of Appeals, was correct in finding lack of applicability of the terms "safe" and "effective" to a class of terminally ill cancer patients.

(2) Laetrile is not subject to the "effectiveness" requirements of the Federal Food, Drug and Cosmetic Act by virtue of its exclusion from such requirements by the 1962 "grandfather clause." The district court examined the administrative record and, after finding that the adminis-

¹ (Continued)

and death, numerous side-effects can occur from this drug, including destruction of immune systems, leukopenia, hemorrhage, gonadal suppression, resulting in amenorrhea or azoospermia, possibly "irreversible." The drug is not represented to be cancer-curative.

ADRIAMYCIN (Adria Laboratories, Inc.) — The FDA-approved data on "safety" states that special attention "must be given to the cardiac toxicity" exhibited by this drug. Such labeling data further states that "Congestive heart failure and/or cardiomyopathy may be encountered several weeks after discontinuation" of therapy with this drug, and that cardiac failure is often "not favorably affected by presently known medical or physical therapy for cardiac support." According to such labeling, there is a "high incidence of bone marrow depression" and administration of the drug "may result in superinfection or hemorrhage." Numerous severe and body-damaging ad-

trative proceeding was not conducted properly, further concluded that Laetrile was exempt by virtue of the 1962 grandfather clause.

Laetrile meets each and every requirement of the grandfather clause. Laetrile and Amygdalin are chemically identical and the evidence of record establishes that Laetrile was commercially available prior to October 10, 1962. During the time frame prior to 1962, Laetrile was generally recognized by experts as safe for its intended use. Labeling for Laetrile is the same as that utilized prior to 1962. Laetrile was not covered by an effective NDA under the 1938 Act.

The district court's examination of the administrative record and its opinion setting aside said administrative findings is well supported in the law. Although the FDA possesses initial jurisdiction to determine whether a substance is a "new drug" within the Act's meaning, such determination is reviewable by the district court under the Administrative Procedure Act, 5 U.S.C., Sec. 701, et seq. The

¹ (Continued)

verse reactions are also listed in the approved labeling, including acute nausea and vomiting, phlebosclerosis, severe cellulitis, vesication and tissue necrosis (death), fever, chills and anaphylaxis. The drug is not stated to be cancer-curative.

ADRUCIL (Adria Laboratories, Inc.) — According to the manufacturer's FDA-approved "safety" data, this is a "highly toxic drug with a narrow margin of safety." It is further stated that "severe hematologic toxicity, gastro-intestinal hemorrhage, and even death may result" from use of this drug, despite "meticulous selection of patients and careful adjustment of dosage." "Myelosuppression" (bone marrow suppression, particularly spinal) "almost uniformly accompanies a course of adequate therapy" with this drug, according to the aforesaid approved FDA labeling. Other and severe dangerous effects are also described in such labeling.

district court, after examining the administrative proceedings; the record compiled; and the Commissioner's decision (42 Fed. Reg. 39768-398806 (1977)) found the Administrator's decision to be arbitrary, capricious, representing an abuse of discretion and not in accordance with the law.

The Administrative Procedure Act and the appeal provisions provided therein were promulgated by a Congress which realized that, in many instances, an administrative agency has special expertise in its area of control and, therefore, should be given initial opportunity to conduct proper proceedings. Nonetheless, Congress deemed it appropriate, within our legal system, to provide for judicial review of the individual agencies' administrative findings. The FDA has had every opportunity to prepare an adequate record substantiating its longstanding opposition to Laetrile and the court's finding that the FDA failed to do so was made properly within the context of the existing framework for review.

(3) The district court's determination that a denial of the use of Laetrile by terminal cancer patients infringed

¹ (Continued)

BICNU (Bristol Laboratories, Division of Bristol Myers Co.)—According to the FDA-approved "safety" data for this drug, "delayed bone marrow toxicity is the major toxicity." Other and serious side effects and adverse reactions are also listed. Additionally, the drug causes cancer, the FDA-approved labeling stating "BICNU is carcinogenic in rats and mice, producing a marked increase in tumor incidence in doses approximating those employed clinically." Alleged "benefits" are stated to be "palliative."

MITHRACIN (Manufactured by Pfizer Laboratories for the Dome Division, Miles Laboratories, Inc.)—The FDA-approved "safety" data for this product states: "Severe thrombocytopenia, a hemorrhagic tendency and even death may result from the use of Mithracin." It is further stated that a detailed analysis of the clinical data in 1,160

upon their constitutionally guaranteed right to privacy was cited as a separate and independent basis for the lower courts' decision. The privacy right cited by the court flows from the decisions in *Roe v. Wade*, 410 U.S. 113 (1973) and *Doe v. Bolton*, 410 U.S. 179 (1973). Recognition was given to the intentions of the FDA in protecting the public; however, the court found that said intention was not an overriding issue given the fundamental nature of the individual privacy right involved.

The decision of the district court is particularly pertinent when it is noted that the Food and Drug Administration has full statutory power to combat false or fraudulent advertising of ineffectual or unproven drugs under both the Federal Food, Drug, and Cosmetic Act, Misbranded Drugs and Devices, 21 U.S.C.A., Section 352 (1976); and the Federal Trade Commission Act, Dissemination of False Advertisements, 15 U.S.C.A., Section 52 (1975).

¹ (Continued)

patients treated with the drug "indicates that the hemorrhagic syndrome is dose related." The manufacturer also notes, with FDA approval, that with recommended "doses of 30 mcg/kg/day or less for 10 or fewer doses" there is an "associated drug-related mortality rate of 1.6%" (16 patients per 1,000 receiving the drug are killed by the drug, in other words, not their cancer). The FDA-approved death rate from this drug rises to 5.7% (or 57 per 1,000) however, with a higher dosage of "Mithracin" noted in said approved labeling. The approved labeling also designates a veritable host of other dangerous side effects. The drug is not stated to be cancer-curative.

FLUOROURACIL (Hoffman LaRoche, Inc.)—The official FDA-approved "safety" labeling in effect as of August 1, 1978 states: "Severe hematological toxicity, gastrointestinal hemorrhage and even death may result from the use of Fluorouracil despite meticulous selection of patients and careful adjustment of dosage." Numerous other adverse and dangerous reactions and side effects are also listed in such official labeling. Alleged "benefits" are stated to be "palliative", only.

In order to overcome the fundamental right of the plaintiff class, the Government must show a compelling government interest.

The Government's statement of its "compelling government interest" is best set out in the Government's Brief in Chief at page 69:

"There is a compelling governmental interest in maintaining a system for the scientific evaluation of the safety and effectiveness of drugs before they are permitted to be marketed."

Thus, the Government's position can best be characterized as asserting the inflexible position that the Federal Food, Drug, and Cosmetic Act, by virtue of interpretation by the Commissioner, requires a certain "system" for the approval of drugs which allows for no exception nor deviation of any kind regardless of the particular circumstances involved. Such dogmatic reasoning, in the face of patent inapplicability of the "effectiveness" requirements to "terminally ill cancer patients" denotes a lack of sound reasoning in tandem with a continuing and irrational opposition to Laetrile which has persisted within the Food and Drug Administration since the 1950's.

Evidence of the Commissioner's unreasoning opposition to Laetrile is best found in the fact that the Food and Drug Administration outlawed Laetrile based upon the fact that it was a "new drug" without even a shred of evidence to establish the "new drug" status. The FDA expressly admitted the lack of any evidence supporting its "new drug" determination even though it had effectively banned Laetrile for many years (App. 42).

As a matter of fact the compelling state interest urged by the Commissioner in the Government's Brief in Chief is nonexistent. None of the lower courts' rulings has overturned any portion of the Federal Food, Drug, and Cosmetic Act. Rather, the controversy surrounding Laetrile has proceeded in an orderly fashion through the courts and the FDA's administrative machinery all in accord with pertinent law.

The FDA made its initial determination that Laetrile was a new drug. This determination was challenged in the United States District Court for the Western District of Oklahoma and was found lacking. On appeal to the Tenth Circuit Court of Appeals the district court's opinion was affirmed but, according to law, it was determined that if the FDA did not have a proper administrative record the case should be remanded to the FDA to allow an administrative record to be prepared. When it was determined that no administrative record existed the case was remanded to the FDA, which then developed its administrative record and issued a decision adverse to Laetrile.

Appeal from the adverse decision of the Commissioner was taken to the United States District Court for the Western District of Oklahoma which overturned the Commissioner's findings. The district court's decision was affirmed by the Tenth Circuit Court of Appeals in an opinion rendered after the Government appealed to that court.

The Commissioner's powers are in no way curtailed by any action taken by any court in this case. Contrary to the Commissioner's assertions in the Government's Brief in Chief, the Food and Drug Administration has had every

opportunity to present its case to the courts and the fact that the decisions have been adverse to the Food and Drug Administration does not imply that the Commissioner's authority has been curtailed. There can be no argument that the Commissioner's decisions are always subject to judicial review of the kind involved in this particular case.

The assertion by the Government that an affirmation of the Tenth Circuit's opinion would inevitably lead to expansion of the usage of drugs unapproved by the Food and Drug Administration is specious. Such expansion would require both administrative and judicial proceedings in line with those held in the instant case and would, therefore, guarantee protection of the public.

(4) Lastly, and probably most importantly, remains the fact that even this Court with its immense power cannot preclude terminal cancer patients from using Laetrile. The original ban on Laetrile led only to the mass exodus of Americans to Mexico and Europe to obtain treatment with Laetrile. Illegal importation of Laetrile by terminal cancer patients then followed inexorably as they returned to the United States with their supplies of Laetrile for continuing treatment. In some cases the ban actually reduced cancer patients to the status of exiles from their own country. Cancer victims who could not morally break the Customs laws by false swearing were forced to remain outside the United States. And, as if the preceding were not bad enough, the ban on Laetrile prior to Judge Bohanon's temporary order resulted in a black market of Laetrile within this country which was not subject to FDA supervision, inspection or testing.

It goes without saying that the same scenario would prevail were a decision adverse to respondents handed down by the Supreme Court. The net effect of a ruling adverse to respondents would be the redevelopment of a black market for Laetrile within this country which would not be subject to scrutiny by the FDA; an exodus of substantial numbers of cancer victims to Mexico and other countries to receive treatment; violation of Customs laws by terminal cancer patients bringing Laetrile back into this country; and an abandonment of their regular family physicians by Americans leaving this country for treatment.

Such results are not at all speculative. They are supported by the facts existing prior to the implementation by Judge Luther Bohanon of an "affidavit system" allowing terminally ill cancer patients to obtain supplies of Laetrile for their own use.

ARGUMENT

I.

THE SAFETY AND EFFICACY REQUIREMENTS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DO NOT APPLY TO THE PLAINTIFF CLASS OF TERMINALLY ILL CANCER PATIENTS.

The Tenth Circuit Court of Appeals declined to rule upon the "grandfather clause" issue and the constitutional issue of right to privacy which were the premises for the lower courts' ruling. In lieu of that reasoning the Tenth Circuit ruled that the terms "safe" and "effective" (21 U.S.C., Section 321(p)(1)) do not apply to the use of the intravenous form of Laetrile by the plaintiff class of terminally ill cancer patients when under a doctor's supervision.

No authority was cited by the Tenth Circuit for the above premise other than the logical statement that "safe" and "effective" would have no meaning to a terminal cancer patient who has been told that he is going to die anyway. The court went on to state that there was no applicable or reasonable measure of safety or efficacy against which to test Laetrile.

The court's reasoning is supported by cases cited by the Government. *Trans Alaska Pipeline Rate Case*, 436 U.S. 631, 643 (1978), quoting *Commissioner v. Brown*, 380 U.S. 563, 571 (1965); *United States v. Key*, 397 U.S. 322, 324-325 (1970); *TVA v. Hill*, 437 U.S. 153, 188 (1978).

The cited cases stand for the proposition that a statute may be construed and implied exceptions found if to do

otherwise "would lead to absurd results * * * or would thwart the obvious purpose of the statute" or in order to avoid an obvious inconsistency within the statutory scheme.

To construe the Federal Food, Drug, and Cosmetic Act to require "effectiveness" of a drug intended for use by a patient certified as terminally ill by his physician, would lead to a most patently absurd result. If there were efficacious drugs then there would be no "terminally ill" cancer patients.

Basic to the arguments being presented to the Court by petitioner herein is the "rosy", but totally unjustified "imputation" that with orthodox, or conventional, cancer therapies we are rapidly winning the battle against cancer, and that, therefore, we need look no further to such therapies as those afforded by Laetrile, and its accompanying metabolic therapies as employed by physicians throughout the United States, and over the World. However, the Government's own statements and statistics demonstrate that we are not winning the battle against cancer, but losing it very rapidly, the conventional therapies being totally inadequate to handle the problem.

In 1977, 400,000 Americans died of cancer, a figure which is seven times the total fatalities in the Vietnam and Korean wars. According to Dr. Marvin Schneiderman, Associate Director of the National Cancer Institute, the death rate from all types of cancer is continuing to increase. Dr. Schneiderman also states that cancer mortality, overall, is increasing, so that it is the only major cause of death which has continued to rise from 1900 through

1976. Putting it another way, more people are dying today from cancer in every age group than have died from cancer in such age groups at any other time in American history. According to present projections 1 in 4 Americans is doomed to die of cancer. Pursuant to the best available government statistics, the cancer death rate in 1900 was 64 per 100,000 of the population, a figure which has now increased to 162.8 per 100,000, or almost a three-times increase. As recently as 1965, the cancer death rate per 100,000 persons was only 127.9. Within the overall statistics, there are equally unfavorable figures as to specific types of cancer. For example, between 1973 and 1975, the number of lung cancer cases increased in the United States 13%, and breast cancer, 17%, stomach cancer, 28%, and prostate cancer, 32%, for the same period. Nor is median survival time particularly encouraging for the cancer sufferer. According to the U. S. Department of Health, Education, and Welfare, the observed median survival time in approximately 219,500 cases of cancer (all sites) was 1.7 years. This median survival time includes those cases wherein a cancer is localized, or limited to the site of origin. Of great interest, however, are the statistics concerning distant (disseminated or "metastasized") cancer, wherein the U. S. Government has stated that the five-year relative survival rate ranges from a maximum of 17% for prostate cancer, to 14% for corpus uteri cancer, 12% for cervix uteri cancer, 10% for female breast cancer, 8% for ovary cancer, 5% for colon cancer, 4% for rectum and bladder cancer, 2% for stomach cancer, 1% for lung and bronchus cancer, and a "zero" survival rate for pancreas cancer for that period. The overall death rate for

those afflicted by distant or disseminated cancers, after a period of five years, is 91%.²

Respondents consider this latter figure to be of particular significance, due to the fact that the respondents, together with thousands of other patients who have availed themselves of Laetrile or amygdalin are "terminal." No conventional therapy is of any avail to prolong their lives beyond the dismal life span shown by the Government's statistics, and which inescapably reflect the inadequacy and inefficacy of conventional cancer therapies.

In this connection the petitioner agency apparently believes that cancer patients should willingly and cheerfully die, rather than have Laetrile. In the Administrative Rule Making Hearing on Laetrile, held by FDA on May 2, 1977, Dr. Samuel C. Klagsbrun participated on behalf of the Agency. (Hrg. transcript, page 60, et seq.)

Although a medical doctor, Dr. Klagsbrun does not treat his patients to get them well, but specializes in "helping cancer patients to die." Concerning conventional therapies for cancer, Dr. Klagsbrun stated (page 65): "the odds are slim, we know that, you are not talking to somebody who thinks it is a terrific thing that we have." Nevertheless, Dr. Klagsbrun proudly testified as to successfully

² See testimony of Dr. Marvin Schneiderman, Associate Director, National Cancer Institute, March 5, 1979, before Special Subcommittee, U.S. Senate, Edward Kennedy, Chairman; "Facts of Life and Death"; U.S. Department of Health, Education and Welfare Publication No. (HRA) 74-1222; "Mortality Trends for Leading Causes of Death"; U.S. Department of Health, Education, and Welfare Publication No. (HRA) 74-1853; "Ca-A Cancer Journal for Clinicians"; "Cancer Rates and Risks", 2nd Edition, U.S. Department of Health, Education, and Welfare.

discouraging cancer patients from seeking alternate therapies in Mexico, or elsewhere, and in two instances which he noted had been "successful" in convincing the terminal cancer patient to die rather than opt for an alternative therapy.

This conclusion that cancer patients should willingly die rather than seek alternate therapy lies at the heart of what is involved herein! When a cancer patient is terminally ill from cancer, when orthodox treatments can offer nothing, then the terminal cancer patient has the inalienable right and final choice to choose Dr. Klagsbrun's "success" in dying, or to choose an alternate cancer therapy, involving Laetrile, after informed consent by the administering physician.

The Government cites certain portions of the Congressional proceedings leading to the 1962 efficacy amendments as support for its position that the term "effective" would apply to Laetrile. The Government cites remarks of Senator Kefauver to the effect that the Act would apply to experimental drugs used to treat "cancer in its last stages." 108 Cong. Rec. 17399 (1962). For further support the Government cites comments of Senator Eastland to the effect that "fatal diseases, such as cancer" would be subject to the Act's requirements, noting that approval of such drugs would be appropriate even though they might only prolong life or alleviate suffering. 108 Cong. Rec. 17401 (1962).

It appears that both Kefauver and Eastland were referring to cancer as a disease with a potentially fatal propensity. There is nothing in the language cited to indicate

that either Senator was referring to cancer in its "terminal" state.

Nonetheless, Senator Eastland's remarks are particularly helpful in noting that approval of such drugs would be proper if they did no more than prolong life or alleviate suffering.

The administrative record compiled by the FDA is replete with evidence of the "pain-killing" effect of Laetrile.³

Neither the Commissioner's findings nor any brief filed by the Government attacks the analgesic effect of Laetrile. In point of fact, the Commissioner's opinion merely notes the fact that claims have been made for the analgesic effect of Laetrile and does not attempt to rebut same. The Commissioner remains content to review affidavits from established medical entities and organizations that Laetrile is not "generally recognized as safe and effective." None of the anti-Laetrile doctors could testify of their own usage of the drug nor of their evaluation of patients who had used the drug to determine if there were an analgesic effect

³ Laetrile, Administrative Rule Making Hearing, Oral Argument, Carole M. Dunn, pp. 100-108, at 100:

"First, here are the observations of David Rubin, M.D., a surgeon at the Beilinson Hospital and a cancer researcher at the Hadassah, Jerusalem, Israel; and Myron N. Issahery, M.D., senior medical consultant to Israel aircraft industries:

"One, with few exceptions all the cases they saw were advanced, incurable cancer patients. Most of them had had conventional therapy before being treated with Laetrile.

"Two, their most striking observation was relief of pain, accompanied by a decrease or even cessation of the need for pain killers and sleeping potions."

See also, the remainder of Ms. Dunn's testimony relative to the analgesic effect of Laetrile, particularly the effect found by Mrs. Dunn in treatment of her own cancer.

which would bring Laetrile within the "effective" classification of the Act as perceived by Senator Eastland.

Thus, even assuming the FDA's own assertion that, the term "effective" has some meaning to terminal cancer patients, Laetrile meets that requirement within the framework established by the Food and Drug Administration.

The determination of the safety of Laetrile as considered by the district court was dismissed by the Government in its Brief in Chief by the following language at 55:

"It was error for the Court to ignore the considered opinions of leading cancer specialists on which the Commissioner relied, and to accept instead the anecdotal experiences of a handful of Laetrile practitioners who themselves are not qualified experts."

³ (Continued)

Testimony of Norma Manke at 225-226:

"Before going on the program I was unable to get out of bed. I felt so bad I didn't want to live and that was four or five months ago. Today I feel well."

Testimony of Maxine Meyers, pp. 281-289, at 287, in reference to Mrs. Meyers' husband:

"After three months on the FU5, the doctor told us there was nothing more to do and he was sent home from the hospital to die at home. I was told he had only a few days to live.

"Instead, one of my sons and I took him to Mexico to the Delmar Hospital for the Laetrile treatment. He was taken off all drugs and medication except Laetrile and enzymes. Within two days, he was able to get out of bed and walk outside. His appetite returned. His mind cleared. And above all else, the pain went away."

Testimony of Philip E. Binzel, Jr., M.D., 360-364 at 362:

"That nutritional therapy has improved the quality of life, for whatever time there may be left for most of those patients, there can be no doubt."

See also, report of David Rubin, M.D., Administrative Record 510, ex. 12.

Contrary to the allegations of the Commissioner, the district court considered the entire record, not merely anecdotal evidence and in support of its ruling enunciated two extensive footnotes, numbers 23 and 24, which are reproduced (our Footnote 4) hereafter verbatim:⁴

Thus, assuming that the term "safe" has some meaning to terminal cancer patients the administrative record bears sufficient evidence of the safety of Laetrile to amply justify the ruling by the district court and by the Tenth Circuit Court of Appeals.

⁴ "[²³] In the only laboratory study of record specifically designed to determine the drug's toxicity, it was observed: "Amygdalin, at all doses studied, appears to be completely non-toxic in laboratory mice." Harold W. Manner, Ph.D., Chairman, Department of Biology, Loyola University, Chicago, Illinois (R 262). Of the various controversial tests studying Laetrile's efficacy on animal tumors, none have disclosed toxicity at reasonable dosage levels.

Among the numerous scientists and physicians testifying from first-hand experience with Laetrile and its effect on humans, unanimity exists as to its nontoxicity.

Dr. Phillip Binzel, M.D., graduate of St. Louis University, testified that he has personally given nearly 4,000 intravenous injections of Amygdalin using doses up to 9 grams without any adverse reaction. (Tr. 363)

Daniel S. Martin, M.D., who participated in the same Sloan-Kettering experiments in which Dr. Sugiura detected cancer inhibiting properties in Laetrile, and who disputed Dr. Sugiura's results, nonetheless concluded that there was no doubt that Laetrile was nontoxic, at least if administered parenterally. (Tr. 437)

Charles Gurchot, Ph.D., testified for the record in affidavit form that Amygdalin in liquid and solid form was used prior to 1962 (between 1934 and 1945) by Gurchot, under the supervision of five named medical doctors at the University of California Medical School at San Francisco. This Amygdalin was, according to his statement, administered "on patients intramuscularly and intravenously." He further stated that during this same period Amygdalin was being used to his personal knowledge by approximately a dozen California physicians in their treatment of cancer. Gurchot expressed his belief that Amy-

II.

LAETRILE IS EXEMPTED FROM THE "EFFECTIVENESS" REQUIREMENTS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BY VIRTUE OF THE TRANSITIONAL PROVISIONS OF THE 1962 AMENDMENTS TO SAID ACT.

A. *The District Court's review of the administrative record and the decision promulgated by the Commissioner of Food and Drugs was well within the scope of review as set out in the Administrative Procedure Act.*

Although the Food and Drug Administration possesses initial jurisdiction to determine whether a substance is a "new drug" within the Act's meaning, *Weinberger v. Hynson, Wescott & Dunning*, 412 U.S. 609, 627 (1973), such determination is properly reviewable by a district court under the Administrative Procedure Act, 5 U.S.C., Section 701, et seq.; *Weinberger*, supra.

In order to be affirmed the agency decision must not be arbitrary, capricious or abusive of agency discretion.

⁴ (Continued)

gdalin was generally recognized by experts as being safe for use in the treatment of cancer on or prior to October 10, 1962. (R 302 at J-206)

Chauncey D. Leake, Ph.D., indicated in his affidavit that he is familiar with Dr. Gurchor's use of Amygdalin in the mid 1930's and 1940's at the University of California Medical School Hospital in San Francisco. He further indicates that physicians and other scientists familiar with Amygdalin recognized it as safe at that time. (R 302 at J-200)

Dr Dean Burk, former head of the Cytochemistry Section, National Cancer Institute, Bethesda, Maryland, after testing Amygdalin on rats, says the substance is "notably less toxic to animal organisms than ordinary diet sugar," and that aspirin tablets are 20 times more toxic than an equivalent amount of Amygdalin. (R 183 at 166F)

"Investigators have found that intravenous doses in excess of 20 grams have been without toxic effect in healthy human subjects, al-

Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971). The court must also consider whether the decision was based upon a consideration of all the relevant factors and whether there has been a clear error of judgment. *Citizens to Preserve Overton Park v. Volpe*, *supra*.

And, the reviewing court has the responsibility "to engage in a substantial inquiry" and "this inquiry into the facts is to be searching and careful." *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 35-36 (D.C. Cir. 1976).

The court should intervene where it appears from a combination of danger signals, that the agency really has not taken a "hard look" at the salient problems, and has not genuinely engaged in reasoned decision-making. *Greater Boston Television Corp. v. F. C. C.*, 444 F.2d 841, 851 (D.C. Cir. 1970).

The lower court upon its review of the decision of the Commissioner of Food and Drugs concluded that said

⁵ (Continued)

though occasionally a mild hypotensive effect may be observed. Repeatedly, studies have indicated that pure Amygdalin, when administered parenterally is astonishingly devoid of toxic effects." (R 183 at 166F)

Donald C. Thompson, M.D., of Morristown, Tennessee, testified as to his personal experience with administering Laetrile to patients and affirmed the drug's nontoxicity. (R 515)

In his report entitled "Use of Laetrile in the Prevention and Treatment of Cancer," Dr. David Rubin, M.D., surgeon at Beilinson Hospital and cancer researcher at Hadassah Hospital in Jerusalem, Israel, asserts: "Laetrile is nontoxic even in very large injected doses." (R 510, Ex. 12)

As another example of a practicing physician who has extensively used Amygdalin and determined it to be nontoxic, see the letter of

decision was arbitrary, capricious, that it represented an abuse of discretion, and that it was not in accordance with law. The court then set aside and vacated the Commissioner's decision.

The court's decision to set aside the Commissioner's findings is well justified when all the pertinent facts are considered. The court noted in its footnote No. 5 the lack of objectivity of the FDA:

"When this suit was initiated, FDA had declared Laetrile a 'new drug' without ever having constructed an administrative record in support of such designation. See *Rutherford v. United States*, 424 F.Supp. 105 (W.D. Okla. 1977). Ideally, agency decisions and conclusions should flow from a probing and objective analysis of a carefully amassed and encompassing factual record. When ordered on remand to conduct an appropriate investigation, FDA begrudgingly announ-

⁴ (Continued)

The Honorable Lawrence P. McDonald, Congressional Representative from Georgia. (R 509 at N265-68)

"Amygdalin (Laetrile) is totally non-toxic systemically, at commonly applied dosages." Hans A. Nieper, M.D., Hannover, West Germany. (R 302 at J-180)

While a doctor's inability to control many variables potentially relevant to curing a disease may impugn the credibility of his perceptions as to a drug's efficacy (*see Weinberger v. Hynson, supra*) his observations as to its toxicity are much more reliable, since the relevant variables are more manageable.

"(Laetrile) is totally nontoxic. Its lethal dose in mice and rats, by injection, is about 25,000 milligrams per kilogram of body weight. It is so nearly nontoxic that in some studies the water, used as a diluent presents a greater toxicity than the vitamin." *The Journal of Applied Nutrition*, Ernst T. Krebs, Jr. (R 302 at J-187)

". . . All the available facts indicate that Amygdalin is essentially non-toxic to laboratory animals and to humans." Raymond Ewell, Ph.D. in chemistry from Princeton, retired professor from the State University of New York at Buffalo. (R 302 at J-196)

ced its intentions to do so and then previous to ever having received the evidence on which its conclusions are ostensibly based, FDA reaffirmed its same, entrenched positions on the salient issues in the case. See "Laetrile—Notice of Administrative Rule Making Hearing," (R 1, 42 Fed. Reg. 10066 (1977)). Understandably, many contributors to the administrative record expressed skepticism concerning the proceedings' fairness."

The FDA, however, was not content to republish its previous position in the administrative record, a further step was taken in publishing and distributing a booklet entitled "Laetrile—The Making of a Myth," a booklet which is highly critical of Laetrile, in the time frame after this case had been remanded to the FDA to make its impartial determination of the status of Laetrile.

The administrative proceeding itself belies an open-minded review by the Food and Drug Administration. The

⁴ (Continued)

[²⁴] "Among experts qualified by scientific training and experience to evaluate the safety of chemical substances in drugs, it is my information and belief that at least since the 1930's pure amygdalin has been generally recognized as safe for use by human beings either by injection, intravenously or intramuscularly, or by oral intake. For example, pure amygdalin may be administered without adverse effect in amounts of 10 grams per day, orally or 3 grams intravenously to a 150 pound man. . ." Charles Gurchot, Ph.D. (R 302 at J-211 and 212)

The authoritative publication, *The Dispensatory of the United States* (1950 ed. p. 40) emphasizes that "Amygdalin itself is practically non-toxic . . ." *Synopsis of Materia Medica, Toxicology and Pharmacology*, C. V. Mosby Company, 1944, p. 33, affirms that "the glucoside Amygdalin, given by injection, produces no harmful effects." (R 183 at 166F)

"With 45 years of study and research on the cancer problem, . . . I have found no statements of data on demonstrated, sustained pharmacological harmfulness to human beings of amygdalin at any dosages

Food and Drug Administration has promulgated regulations providing for hearings in the event of referral by court. 21 C.F.R., Sec. 10.60. The hearings provided range from very formal to very informal. The Commissioner of Food and Drugs elected to conduct hearings in the matter of Laetrile under the provisions for the most informal proceedings allowed by law. These informal proceedings resulted in a denial to respondents of the right to cross-examine witnesses and allowed testimony to be given without requiring the administration of an oath. Respondents' attorneys objected to this procedure but the Hearing Examiner elected to proceed nevertheless (Administrative Rule Making Hearing, Oral Argument, pp. 10, 11, 27 and 28).

The FDA's selection of its least formal and, therefore, least probative administrative proceeding is especially indicative of the FDA's lack of objectivity when it is taken

⁴ (Continued)

recommended or employed by physicians in the United States and abroad, up to the high level of 200 miligrams per kilogram of body weight per day (equals 15 grams—75 kilogram man-day), administered either orally or parenterally; and, more specifically no such statements by official opponents of the use by humans of amygdalin, including comment in their major publications. Few substances have been so widely investigated regarding non-toxicity and chemical definition as has amygdalin, by pharmacologists and chemists in many countries of the world, for over 125 years. . . . Amygdalin has been known and widely recognized for over one hundred years as nontoxic for man." Dean Burk, Ph.D., from the pamphlet *Vitamin B-17 . . . a Brief on Foods and Vitamins.* (R 302 at J-69 and J-65)

In its 1963 "Report on the Treatment of Cancer with Beta Cyano-genetic Glucosides ('Laetries')" the only potential danger discerned by the Cancer Advisory Council of the State of California was "that the use of one or more of these substances in early cancer, to the exclusion of conventional treatment might well be dangerous since treatment with acceptable, curative methods (surgery or radiation)

into consideration that the Tenth Circuit Court of Appeals required a hearing which would guarantee cross-examination.

The Tenth Circuit in its Order on Remand held that a hearing pursuant to 5 U.S.C.A., Section 554(c) would be required. *Rutherford v. U.S.*, 542 F.2d 1137 (10th Cir. 1976).

The cited provision, 5 U.S.C.A., Section 554(c), contains a provision that hearings conducted thereunder must be pursuant to provisions of Sections 556 and 557 of the Act. Section 556 of the Act provides under sub-part (d) that:

" . . . a party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts . . . "

⁴ (Continued)

would thereby be delayed potentially until such time as metastases were manifest and the cancer might therefore no longer be curable. (R 183 at 246F) No toxicity was reported in the 1953 case study report of the Cancer Commission of California Medical Association.

It is only within the context of FDA's creation of this record that the specter of Laetrile's toxicity has even been raised. The drug's reputation for nontoxicity, even among its opponents, is amply documented. See, for example: "Harmless, but Ineffective Remedies," *The Journal of Pharmaceutical Sciences*, Oct., 1975. (R 180 at 190E) FDA allegations of toxicity appear to be more of an afterthought offered to bolster their other conclusions, rather than a reasoned conclusion based on a detached, impartial view of the record.

While apricot kernels can be poisonous if ingested in very large quantities, such contain enzymes not present in Amygdalin; thus, the toxicity of apricot kernels and Amygdalin are not comparable. Deposition of Raymond Ewell, Ph.D. (R 302 at J-197)"

The FDA denied respondents their right of cross-examination which had been mandated by the Tenth Circuit Court of Appeals and generally carried out the proceedings in such a way as to guarantee that the FDA's position would prevail.

It is no wonder that the district court found the Commissioner's decision to be arbitrary, capricious, representing an abuse of discretion and not in accordance with law.

B. Laetrile is exempted from the requirements of the Federal Food, Drug, and Cosmetic Act by virtue of the 1962 grandfather clause.

The burden of establishing that Laetrile is a "new drug" is upon the Food and Drug Administration. The case *Durovic v. Richardson*, 479 F.2d 242 (7th Cir. 1973), contained the following language regarding the meaning of "commercially" available within the grandfather clause exemption:

"We assume since Congress was endeavoring to avoid imposing new burdens on drugs which had already achieved 'recognized' status, and usage thereunder to a material extent and for a material time, that a gloss of openly and readily available and broadly distributed in the ordinary course of business as well as lack of restriction to investigational use was intended."

The court then placed the burden of proof squarely upon the FDA:

"Nevertheless we find it impossible to say, on the record presented, that defendants conclusively established that Krebozen was not 'commercially used or sold' as of October 9, 1962."

The *Durovic* view is strengthened by the order of the Tenth Circuit Court of Appeals upon its remand of the case to the Food and Drug Administration. *Rutherford v. United States*, 424 F.2d 1137 (10th Cir. 1976):

"To support its determination, the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as 'safe and effective' and that Laetrile is not grandfathered by either of the exemptions discussed above."

The standard by which the district court was required to examine the administrative record is found in the case *United States v. Seven Cartons, More or Less, etc.*, 293 F.Supp. 660 (S.D. Ill. 1968):

"It could be expected that genuinely honest differences in expert opinion on the safety and effectiveness might exist with reference to most drug compounds.

"When such genuine differences of expert opinion addressed to the relevant factual question are expressed in opposed affidavits, the case is not a proper case for summary judgment. That conflict of opinion seems to present a genuine issue of fact for trial.

"The government argues that the rule stated in *Merritt* and subsequent cases is compelled by the state's purpose of protection of the public health. The court does not agree. The statutory purpose is served by an orderly judicial procedure. It cannot justify the decision of factual issues by summary judgment. Where, as here, each party has submitted affidavits in support of its position the court must examine those affidavits to determine whether a genuine difference of expert opinion is presented. If such difference of opinion appears, decision must abide the results of a trial on the issues."

In this case, United States District Judge Bohanon acted as both the trier of fact and law. It then became his prerogative to examine the opposing affidavits and materials in the administrative record and make his determination based upon them.

Thus, with affidavits and other supporting materials asserted by both the petitioners and respondents on the issue of general recognition as safe and effective, the district court acting as the trier of law properly reviewed the materials and set aside the Commissioner's decision.

In order to qualify as a "grandfathered" drug under the transitional provisions of the 1962 amendments to the Federal Food, Drug and Cosmetic Act, Section 107(c)(4) of the drug amendments of 1962, Pub. L. No. 87-781 (76 Stat. 789), it is required that the drug was (1) commercially used or sold in the United States on the day immediately preceding the enactment date of October 10, 1962; (2) the drug was not a new drug as defined by 201(p) of the basic Act then in force; and (3) the drug was not covered by an effective new drug application. If the above requirements are met the efficacy amendment will not apply to such drug when it is intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug.

(1) Laetrile and Amygdalin are synonymous.

The Commissioner recognized the content of the substance which was the subject of his rule-making proceeding when the first notice of rule making was published, 42 Fed. Reg. 10066 (1977):

"Laetrile is the name of a product whose major component or ingredient is Amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds and in other plant material . . . and it has been known, tested and used [as a cancer remedy] for more than twenty-five years. . . ."

The district court found that there was no real question as to the chemical composition of Laetrile. The chemical identity of Laetrile and Amygdalin is documented fully in the opinion of the United States District Court for the Western District of Oklahoma at footnote 17.

In addition to the sources cited by the district court in its determination that Laetrile and Amygdalin are synonymous is the especially compelling admission of the FDA in its January, 1977 publication, "Laetrile—The Making of a Myth" in which the FDA states:

"Laetrile is the chemical Amygdalin, which occurs naturally in the pits of peaches, apricots, and bitter almonds and other plant material."

The illusory distinction the Commissioner asserts between Laetrile and Amygdalin is nothing more than a red herring intended to obfuscate the real issues before the Court.

(2) Laetrile was commercially used or sold in the United States prior to the enactment of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act.

The commercial availability of Laetrile prior to 1962 is well documented in the opinion of the United States District Court for the Western District of Oklahoma, footnote 21.

Laetrile was also listed in the 1907 and 1940 Merck Index, an encyclopedia for Chemists, Pharmacists and Physicians. Amygdalin was listed in the 1907 Index at page 63 and in the 1940 Index at page 38.

All drugs listed in the Merck Index are available to Pharmacists and Physicians thus establishing unequivocally that Laetrile was commercially sold prior to the 1962 Amendments to the Food, Drug and Cosmetic Act.

Even the Food and Drug Administration recognizes that Laetrile has been available prior to 1962. During one of the initial proceedings, in which a temporary injunction was granted to Plaintiff Glen Rutherford, on July 18, 1975, the Government's attorney, Mr. Jay Geller represented to the court as follows:

"Mr. Geller: With respect to this particular drug, as the court is probably able to tell from all the materials submitted by Mr. Watts last week, this particular substance has been around for a long time.

The Court: 1820, I think.

Mr. Geller: At least 25 years, that it has been in current vogue . . ."

The district court also noted that the FDA had placed certain restrictions on the commercial availability and use of Laetrile previous to July 29, 1977, the date on which the Administrative Record and Commissioner's decision were filed and that such restrictions were totally unsupported by any Administrative record whatsoever and were therefore, subject to attack as a matter of law.

The court, thus draws attention to the fact that the FDA implemented an illegal ban on Laetrile because its determination was not based on proper administrative proceedings. The FDA then used the fact of its ban to support its position that Laetrile was not commercially used or sold prior to the enactment of the 1962 Amendments. Such action is of itself arbitrary and capricious.

(3) Laetrile was generally recognized as safe, by experts qualified by experience and training, prior to the 1962 Amendments to the Food, Drug and Cosmetic Act.

In order for Laetrile to be exempted by the 1962 Amendments to the Food, Drug and Cosmetic Act, it must have been "generally recognized as safe" by qualified experts prior to 1962. *Durovic v. Richardson*, supra, at 250. The court's decision that Laetrile was generally recognized as safe prior to the adoption of the 1962 Amendments is supported by its lengthy footnote 24 set out previously in this brief as footnote 4 at pages 29-31.

The district court comments at footnote 23:

"Among the numerous scientists and physicians testifying from firsthand experience with Laetrile and its effect upon humans, unanimity exists as to its non-toxicity."

In response to the above, the petitioner states at page 46 of its Brief in Chief that there was no such "general recognition of safety," because "Laetrile was not generally known at all to the community of medical experts."

In the first place, there is no "community" of medical experts, anymore than there is "community" of lawyers, teachers, or butchers, speaking in unison, on a given subject.

Whatever the case, no provision whatsoever of the Food, Drug and Cosmetic Act provides that merely because "experts" know nothing of the substance, that this obviates "general recognition" by those who are actually qualified to express an opinion.

The pertinent provisions of the Federal Food, Drug and Cosmetic Act as it was in effect on October 9, 1962, designated a criterion of "general recognition of safety" by "experts qualified by scientific training and experience" to evaluate the safety of a substance. Section 201(p) of the Act, 21 U.S.C. (1958 Ed.) 321(p).

It is submitted that the ignorance of the Government's experts regarding the general recognition of safety of Laetrile cannot constitute the required "experience" mandated by the statute, and therefore, only experts having real knowledge of Laetrile can be qualified to express opinions concerning its safety.

Regardless of the validity of the views of the Government's experts, the various testimony and affidavits presented by petitioner and respondent were properly reviewed by the United States District Court for the Western District of Oklahoma under applicable law. *United States*

v. 41 Cases, *More or Less*, 420 F.2d 1126 (5th Cir. 1970), provides the standard of review:

"... disagreement of experts as to the general recognition of a drug as being safe only creates a fact question for the jury, *United States v. Articles of Drug Labeled in Part Quick-O-Ver*, *supra* at 448."

See also, *United States v. Seven Cartons, More or Less, Etc.*, *supra*, at 33.

Thus, Judge Bohanon, acting as the trier of fact, determined that the administrative record supported the view that Laetrile was generally recognized as "safe," by experts qualified by training and experience, prior to the adoption of the 1962 Amendments to the Act.

(4) Laetrile meets the labeling requirements of the 1962 Amendments to the Federal Food, Drug and Cosmetic Act.

Initially, the district court pointed out that the FDA erred as a matter of law in its assertion that Laetrile cannot escape new drug classification unless it is shown that "it is currently intended solely for use under conditions prescribed, recommended or suggested in its labeling on October 9, 1962." The court analogized this situation to that of aspirin, finding that such interpretation of the Act would render all aspirin, regardless of the use, to be subject to classification as a new drug if *any* aspirin were promoted for a use not intended prior to 1962.

Contrary to the findings of the Commissioner of the Food and Drug Administration, the court found that appropriate statutory construction required that Laetrile be

considered exempt from "new drug" status to the extent that it is currently being used for the same purposes and under the same conditions and labeling as on October 9, 1962.

After pointing out the FDA's legal error, the district court goes on to set out the purposes for which Laetrile is not a new drug in footnote 7 of its opinion:

"1962 labeling characterizes Laetrile as a palliative agent for use in 'cancers beyond aid by standard agents,' and warns that 'it is not to be employed to the exclusion of surgery, radiation or similar standard modalities so long as they are indicated.' Affidavit of Robert S. K. Young, Ph.D. (R 201 at H 234). If 'generally recognized as safe' by qualified experts, the '1962 grandfather clause' prevents Laetrile from being classified or treated as a 'new drug' when labeled in substantially the same manner as previous to October 10, 1962. . . ."

C. Congress did not intend for the "safety" and "efficacy" requirements to apply to the respondent class of terminally ill cancer patients.

The Kefauver-Harris Amendment to the Federal Food, Drug and Cosmetic Act added, *inter alia*, the requirement that drugs be "effective" in addition to the requirement that they be safe. 21 U.S.C.A., Section 355.

The legislative history and judicial interpretation of the efficacy requirement reveals that Congress' intent was to provide protection for consumers of prescription drugs from the economic and the physiological consequences of ineffective medication. The imposition of the additional burden on the drug industry was the subject of extensive

discussions and hearings before the Congressional Committees. See, *Hearings on S.1552 before the Senate Subcommittee on Anti Trust and Monopoly of the Committee on the Judiciary*, 87th Cong., 1st Sess.1962 (1962).

The efficacy requirement resulted in the licensing procedure for new drugs becoming prohibitively expensive. Culbert, *Freedom from Cancer*, 114 (1976):

"By 1976, it was generally conceded that to meet the compliance of FDA 'safety' and 'efficacy' guidelines in securing licensing of new 'entities,' no less than ten years of trials both animal and human, nor less than 14 to 15 million dollars in expenditures, nor less than 80 thousand pages of paperwork were needed!"

Drug manufacturers are not in a position to spend the time or money required to obtain an NDA for Laetrile. The drug companies would need the assurance that they could obtain a patent on the substance in order to recoup the monies expended in the testing of Laetrile. No such guarantee exists, primarily because Amygdalin occurs naturally in hundreds of plants and also because the substance is being manufactured in Mexico and other countries at the present time.

Also, it would take a very foolhardy drug company, with the knowledge of the FDA's ongoing opposition to Laetrile, to even initiate the testing procedures necessary to obtain an NDA.

Thus, the Federal Food, Drug and Cosmetic Act is being applied not to the drug manufacturers it was intended to apply to, but to a class of terminally ill cancer patients who cannot conceivably afford the extensive testing that is necessary to obtain an NDA.

The sweeping power asserted by the FDA should not be allowed to deny the use of Laetrile by the respondent class of terminally ill cancer patients within the limitations imposed by the lower courts.

III.

**THE FOOD AND DRUG ADMINISTRATION BAN
OF LAETRILE DEPRIVES TERMINALLY ILL CAN-
CER PATIENTS OF THEIR CONSTITUTIONALLY
GUARANTEED RIGHT OF PRIVACY.**

A. *The Right to Privacy extends to use, by terminally ill cancer patients, of the substance Laetrile.*

The Right of Privacy was first enunciated by this Court in *Griswold v. Connecticut*, 381 U.S. 471 (1965). The right has been found to emanate from the penumbras of the 1st, 4th, 5th, 9th and 14th Amendments to the Constitution. *Roe v. Wade*, 410 U.S. 113 (1973). The Privacy Right has been recognized as "fundamental." *Griswold v. Connecticut*, *supra*.

The language of Mr. Justice Brandeis in his dissenting opinion in *Olmstead v. United States*, 277 U.S. 438, 478 (1928), remains vital today:

"The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans and their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone—The most comprehensive of rights and the right most

valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation . . ."

In the case *Application of President and Directors of Georgetown College*, 331 F.2d 1010, 1017 (D.C. App. 1964), Mr. Justice Burger, in his dissent, commented upon the applicability of Mr. Justice Brandeis' concept of the Right of Privacy:

"Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest that he intended to include a great many foolish, unreasonable, and even absurd ideas which do not conform, such as refusing medical treatment, even at great risk."

The right to refuse any and all medical treatment has been recognized by this Court. *Jacobson v. Massachusetts*, 197 U.S. 11 (1904). This same principle has been affirmed even despite risk of death. *Erickson v. Dilgard*, 252 N.Y.S. 2d 705, 706 (1962). The Court in *Erickson* stated:

" . . . it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

To recognize a right to decline medical attention of any kind, while denying a right of terminal cancer patients to utilize the nontoxic substance Laetrile, would create a bizarre anomaly in the law.

The lower courts' decisions allowing intravenous use of Laetrile by terminally ill cancer patients falls within the Right to Privacy previously enunciated by this Court.

This Court has dealt with the privacy right in several recent cases within a health context. *Roe v. Wade*, *supra*; *Doe v. Bolton*, 410 U.S. 179 (1973); *Griswold v. Connecticut*, *supra*; and *Eisenstadt v. Baird*, 465 U.S. 438 (1972).

In *Griswold*, this Court held that the state could not ban the use of contraceptives without abridging a couple's right to privacy which underlies a marriage relationship. This Court recognized the Right of Privacy within the general spirit of health care.

Eisenstadt upheld the right of a person to distribute contraceptives on grounds that a statute prohibiting distribution to single people violated equal protection by distinguishing between the married and single people. The Court stated at 453:

"If the Right of Privacy means anything, it is the right of the individual, married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

In the landmark case, *Roe v. Wade*, *supra*, this Court expanded the Right of Privacy to encompass a woman's decision to have an abortion. The Court found that the right to an abortion was a "fundamental" right.

The decision in *Roe*, *supra*, was based, at least in part, on the health of the mother. *Roe* at 727:

"The detriment that the State would impose upon the pregnant woman by denying this choice altogether is apparent. Specific and direct harm, medically diagnosable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon a woman a distressful life in the future. Psychological harm may be eminent. Mental and physical health may be taxed by child care."

Regardless of the weight given the health factor in *Roe*, the health of the pregnant mother is inextricably involved in the Court's rationale allowing abortions.

In declaring the statutes prohibiting abortion to be unconstitutional this Court balanced that right against what was asserted by many as the Right to Life for the unborn fetus.

Even considering the asserted rights of the unborn fetus this Court did not find them strong enough to deny the mother's right to privacy.

Doe v. Bolton, *supra*, another abortion case handed down by this Court on the same day as *Roe*, also struck down criminal abortion statutes as unconstitutional.

Mr. Justice Douglas in his concurring opinion in *Doe v. Bolton*, 410 U.S. 179, 213 (1973), recognized the fundamental nature of the freedom to care for one's own health:

"Third is the freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll or loaf."

Mr. Justice Douglas commented further about the right to health care at page 219:

"The right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic Fourteenth Amendment values. We deal with fundamental rights and liberties, which, as already noted, can be contained or controlled only by discretely drawn legislation that preserves the 'liberty' and regulates only those phases of the problem of compelling legislative concern."

The privacy right includes the privilege of an individual to plan his own affairs, for "outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, do what he pleases, go where he pleases." *Kent v. Dulles*, 357 U.S. 116, 126 (1958).

The terminally ill cancer patients involved in this case have heard the death sentence from their own doctors. They have been told that orthodox medicine holds no hope for them and that they are suffering from cancer in its "terminal" state. They are perfectly free to decline treatment of any kind, *Jacobson*, supra. Yet, under the construction of the Food, Drug and Cosmetic Act asserted by the Commissioner, they may not seek hope from the nontoxic substance Laetrile.

Those patients with requisite wealth can avoid illegality by obtaining treatment in countries such as Mexico where the treatment is legal, but this alternative is not available to the poor or the bed-ridden.

The ban of Laetrile by the Food and Drug Administration has resulted in a severe limitation on terminal cancer patients exercise of free judgment in matters directly affecting the quality of their lives. It cannot be asserted that these terminal cancer patients are being granted their

"right to be let alone" as long as they are denied free access to Laetrile.

Further, the Government makes no real argument that the use of Laetrile by terminal cancer patients would, in any way, offend the rationale of *Jacobson*, supra, because there is no intrusion upon the "safety of the general public."

The issue is best framed in the language of the district court wherein Judge Bohanon writes at page 27:

"As a nation, however, historically and continuously, we are irrevocably committed to the principle that the individual must be given maximum latitude in determining his own personal destiny.

"To be insensitive to the very fundamental nature of the civil liberties at issue in this case, and the fact that making the choice, regardless of its correctness, is the sole prerogative of the person whose body is being ravaged, is to display slight understanding of the essence of our free society and its constitutional underpinnings. This is notably true where, as here, there are no simple answers or obvious solutions, uncertainty is pervasive, and even the best efforts leave so much to be desired.

"The final consequences are ultimately borne by those whose bodies are the battleground on which cancer's war is waged. Many perceive the drugs acquisition as a life and death matter, and are understandably frustrated and enraged over attempts by their government to deny them the right to decide for themselves questions of such a personal and grave nature."

The court also notes (fn. 10) that not all members of America's leading institutions are opposed to the use of Laetrile. The court cites the affidavit of C. Chester:

"I have stated before, . . . that if the patient has exhausted the benefits of conventional treatment and does not mind the financial outlay, I see no harm in his taking Amygdalin in the way it has generally been used." Affidavit of C. Chester, Ph.D., Vice President and Associate Director for Administrative and Academic Affairs of the Sloan-Kettering Institute for Cancer Research, New York.

It is also significant that nineteen (19) states have promulgated laws permitting and approving the use of Laetrile.⁵

The compelling nature of the health interest invoked by the respondent class of terminally ill cancer patients falls within the spirit and intent of the privacy cases decided by this Court and the same protection should be granted them.

⁵ Alaska (See Alaska Statutes 08.64.367); Arizona (See A.R.S. 36-2451); Delaware (See Del. Code Ann. 16 Section 4901); Florida (See F.S.A. 458.24); Idaho (See Idaho Code 18-7301A); Illinois (See S.H.A. 56½, Section 1801); Indiana (See Burns Ind. St. Ann. 16-8-8-1); Kansas (See S.B. 505 May 8, 1978); Louisiana (See L.S.A.—R.S. 40:676); Maryland (See Ann. Code of MD, Art 43 Sec. 133 ch 809); Nevada (See Nev. Rev. St. 630.303); New Hampshire (See R.S.A. 329:30); New Jersey (See N.J.S.A. 24:6F-1); North Dakota (See H.B. 1214 eff. July 1, 1979); Oklahoma (See 63 Okl. St. Ann. Sec. 2-313); Oregon (See Oregon Rev. St. 689.885); South Dakota (Bill Number 1287 signed 3/16/79 eff. 7-1-79); Texas (See Vernon's Ann. Civ. St. 71 art. 4476-5a.); Washington (See R.C.W.A. 70-54.130).

B. *There is no compelling state interest justifying denial of the use of Laetrile to the respondent class of terminally ill cancer patients.*

In order to justify governmental regulation when a "fundamental right" is involved, there must be a "compelling state interest" and also, the legislative enactments "must be narrowly drawn to express the legitimate state interest at stake." *Roe v. Wade*, supra, at 155.

It is paradoxical that petitioner appears more interested in a potential harm to its "system" of control over drugs than in the issues presented in this case.

The Government argues that the contours of this case are deceptively narrow and that a decision in this case would in effect "cripple" the Food and Drug Administration's ability to administer the Act.

It appears that the Food and Drug Administration is seeking, by painting with very broad strokes, to shore up its indefensible position in this case by asserting across the board applicability to other cases. Such is not the truth.

As pointed out in our summary of argument, the lower courts' decisions have inherent limitations precluding across the board applicability to other drugs. The approval of Laetrile by the lower courts is limited to use by individual terminal cancer patients of the intravenous form of Laetrile under the supervision of a doctor.

Additionally, to apply any decision in this case to other drugs, would require administrative hearings and judicial proceedings as carried out in this case and would, there-

fore, preclude applicability of a decision in this case to other drugs.

The bottom line to the Government's argument in this instance is that the Food and Drug Administration does not want judicial review of its decisions. Instead, it obviously wants a "rubber stamp" on any decision it makes. This is contrary to the law. *Weinberger v. Hynson, Westcott & Dunning*, *supra*; *Citizens to Preserve Overton Park v. Volpe*, *supra*; *Greater Boston Television Corp. v. F. C. C.*, *supra*.

The administrative regulations promulgated by the FDA as asserted by the Commissioner are unyielding. They do not represent regulations which are "narrowly drawn to express only the legitimate state interest at stake."

The application of the "safety" and "efficacy" requirements as enunciated by the Food and Drug Administration is overly broad. As has been argued previously, the term "effective" has little or no significance to a terminal cancer patient and, therefore, its broad and unyielding application to the small class of terminally ill cancer patients violates the principle that the regulation must be "narrowly drawn."

For terminally ill cancer patients to be denied the use of Laetrile because of its asserted ineffectiveness would, if applied across the board, preclude a terminal cancer patient from the usage of any drug for the reason that there could be no effective drug for a terminal cancer patient.

With ample evidence in the record establishing that Laetrile is safe and nontoxic, the ban of Laetrile based on

its "ineffectiveness" offends the respondent class of terminally ill cancer patients' constitutional right of privacy.

Two recent and extensive articles have been published regarding the constitutional question involved herein. Milis, *Government Regulation of Health-Care Drugs of Questionable Efficacy*, 14 San Diego L. Rev. 378 (1977); and Block, *Laetrile: Individual Choice for Cancer Patients*, 7 New York University Review of Law and Social Change, 313 (1978). Both articles reach the conclusion that under certain circumstances at least, the right to privacy encompasses the right to use Laetrile.

Mr. Milis does not deal with terminal cancer patients. Rather, he deals with an individual desiring to use Laetrile in conjunction with standard therapy. Even in this context, he concludes as follows:

"If a fundamental right is at stake, the appropriate standard of review is strict scrutiny. Under this standard, the government's interest in health and safety cannot offset the individual's privacy interest when a drug of questionable efficacy is used merely as a supplemental treatment. Therefore, statutes regulating drugs of questionable efficacy should be more narrowly drawn so as not to infringe upon the rights of supplemental users of a drug like Laetrile. Making such drugs available through professionally staffed agencies would satisfy the health care rights of these individuals, while removing the uncertainty and mystery surrounding unapproved health care. Such an approach would improve the current system by assuring that users of Laetrile-type drugs receive complete and competent medical treatment."

Ms. Block concludes her article as follows:

"The right to choose Laetrile as a form of cancer treatment depends on the degree of constitutional protection given this right. Under the standard of Griswold and Roe, the Laetrile decision is basic to one's life and is, therefore, protected by the fundamental right of privacy. Once that right has been established as fundamental, state law may infringe on it only insofar as necessary to achieve a compelling state interest. For the cancer patient who is terminally ill, who has tried other treatments, and who has no dependents for whom he would otherwise be providing, the state interests are not sufficiently compelling to justify total proscription of Laetrile. These interests can be served best by narrowly drawn regulations of Laetrile that address specific areas of concern and that vary with the different needs of cancer victims."

The compelling state interest in protecting its "system" asserted by the Food and Drug Administration, simply does not exist in this case. The Government's assertion of harm to the FDA's regulatory scheme is predicated upon mere speculation and appears to be founded in the irrational fear that the Commissioner's powers will in some way be limited. The procedural safeguards, both administrative and judicial, as set out above, will provide ample protection for the Commissioner.

IV.

THIS COURT SHOULD DISREGARD REFERENCES TO PUBLICATIONS AND CASE REPORTS WHICH ARE OUTSIDE THE RECORD.

The Government in its Brief in Chief at footnote 8, refers to reports which appeared after the administrative proceeding and which are not a part of the record for review. The Brief Amicus Curiae of the State of California under its Proposition Three, refers to recent events and medical research which are also outside the record and should be ignored by this Court. *New Haven Inclusion Cases*, 399 U.S. 392 (1970).

That this Court should base its review only upon the record reviewed by the district court and the Tenth Circuit Court of Appeals, is axiomatic within appellate procedure.

Respondents have had no opportunity to examine the materials cited by the Government and the State of California, and obviously no opportunity to cross-examine any witnesses to determine the veracity of their statements.

The State of California goes beyond citing literature when it cites the death of Jo Anne Etta Pye, a California resident who purportedly died of cyanide intoxication (Amicus Brief at 20). Ms. Pye's death has been the subject of no judicial proceedings to the best knowledge of respondents and any commentary about the cause of her death is the rankest of hearsay.

Without attempting to refute any of the unproven allegations regarding the death of Ms. Pye, respondents draw the Court's attention to the affidavit of Dr. John A. Rich-

ardson, which is attached hereto as Appendix A, to show that, at least, there is controversy surrounding the actual cause of death of Ms. Pye.

CONCLUSION

This Court should affirm the decision of the Tenth Circuit Court of Appeals allowing terminal cancer patients the use of the intravenous form of Laetrile under a doctor's supervision.

Affirmance is dictated by the premises cited by both the district court and the Tenth Circuit Court of Appeals.

The terms "safe" and "effective" have no meaning, or at least not the meaning asserted by the FDA, to terminally ill cancer patients. Laetrile is exempt from the "efficacy" requirements of the Food, Drug and Cosmetic Act by virtue of the transitional provisions of the 1962 Amendments to the Act. Independent of the above, the lower courts' decisions should be affirmed because to do otherwise would be to violate the constitutionally guaranteed right of privacy of the respondent class of terminally ill cancer patients.

Respectfully submitted,

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KIRKPATRICK W. DILLING
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April, 1979

APPENDIX 'A'

John A. Richardson, M.D.
415 Kains Avenue
Albany, California 94706
415-527-3020

April 2, 1979

AFFIDAVIT

Mr. Ken Coe, Attorney
Looney, Nichols, Johnson & Hayes
300 Lawyers Building
219 Couch Drive
Oklahoma City, Oklahoma 73102

Dear Mr. Coe:

It is now quite apparent from a simple examination of the Emergency Room Laboratory results, from Vesper Memorial Hospital, San Leandro, California, in the case of Mrs. JoAnne Pye, that her death was due to metabolic acidosis which would have responded to the administration of bicarbonate of soda intravenously. Had NaHCO_3 been given to this patient, she would have been able to sit up and walk out of the hospital.

The basis for this opinion is the fact that in the emergency room her blood PH was 6.4, (normal being 7.4); her -HCO_3 was 4, (normal being 25). Fifteen minutes later her -HCO_3 was 2. No where is there evidence that anyone recognized this nor is there evidence that soda bicarb was administered.

Metabolic acidosis does not occur suddenly but takes time to develop and in this case, it would be consistent with the vomiting and diarrhea with which she was afflicted during the entire day of her death.

The point is that had this condition been recognized and treated, Mrs. JoAnne Pye would be alive today and

[APPENDIX]

the speculative argument over the possibility of cyanide intoxication would be of tangential polemics and entirely unrelated.

Please note the attached laboratory record from Vesper Memorial Hospital Emergency Room pertaining to this subject.

Sincerely,

s/ John A. Richardson, M.D.
John A. Richardson, M.D.

[Laboratory Report omitted in printing]

STATE OF CALIFORNIA
COUNTY OF ALAMEDA

Subscribed and sworn before me this 2nd day of April,
1979.

s/ Janice A. Pruett
Janice A. Pruett, Notary Public

[Official Seal of Janice A. Pruett,
Notary Public, appears here.]